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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,294	06/01/2006	Sudhir Paul	UTEX0012UPCT-US	3697

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1652	

NOTIFICATION DATE	DELIVERY MODE
01/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,294	PAUL ET AL.	
	Examiner	Art Unit	
	MD. YOUNUS MEAH	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) *2-5,34-70 and 76-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-33 and 71-75* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/07, 2/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-85 are pending. Applicants' election with traverse of group I (claims 1, 6-33 and 71-75) in their response of 10/14/2008 is acknowledged. The traversal is on the ground(s) that there was no lack of unity with regard to the pending claims and there should not be an undue burden of search to consider all the groups. Applicant's arguments have been fully considered but they are found unpersuasive to withdraw the restriction requirement previously applied. Claims are not linked by a special technical feature, as explained in the election/rejection office action and further evidence that the claims lack special technical feature is found in rejection heading under U.S.C.102 below. Therefore claims 2-5, 34-70 and 76-85 remain withdrawn. Therefore the restriction is maintained and made FINAL.

Sequence compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. For example, the variety of sequences are disclosed in the specification at page 36, line 32 and page 52 line 27 without sequence identification number. Appropriate correction is required. See particularly 37 CFR 1.821(d).

Objection

Claim 1 is objected to having non-elected subject matter. Appropriate correction is required.

35 U.S.C 112 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-33, and 71-75 (dependent on claim 1 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forh below:

Claim 1 is indefinite in reciting covalent antibodies as it is unclear what covalent antibodies is meant because claim 1 produce catalytic antibodies using pCRA, for examination purpose it is considered as catalytic antibodies.

Claim Rejections

***35 U.S.C 112 1st* paragraph rejection**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-7, 11-12,15-23, 25-29, 71-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 6-7, 11-12,15-23, 25-29, 71-75 are directed to a method of

generating catalytic antibodies to polypeptide covalently reactive antigen (PCRA) wherein said PCRA comprise any antigenic polypeptide covalently attached to any transition state analog of any reaction and injecting said antigen to any organism, wherein said antibodies produced shows catalytic activity of any enzyme. The prior art (Taguchi et al. *Biorg and Med chem. Lett*. 2002, 3167-3170) and the specification teach PCRAs (such as compounds in claims 30-33) that produce catalytic antibody having protease activity that cleave peptide bonds. The specification (example 2, page 9) indicates that "A potential weakness is that immunogen does not contain structural feature favoring synthesis of Abs capable of rapid hydrolysis of the acyl-Ab intermediate and product release". For the catalytic antibody reported in the specification, the serine protease-like catalytic activity for peptide-bond cleavage is very low. The specification does not disclose how catalytic antibodies produced by any PCRA comprising any polypeptide epitope can show catalytic activity of any enzyme. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Applicants' are referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 6-7, 11-12,15-23, 25-29, 71-75 are rejected under 35 U.S.C. 112, first

paragraph, because the specification, while being enabling for method of generating catalytic antibodies to the antigen comprising PCRA (i.e., comprising compounds at Fig. 37, 48 or 49 or compound of claims 30-33) wherein said method comprising administering said PCRA to an organism such as mouse and wherein said catalytic antibodies cleave the peptide bond of protease type polypeptide molecule, does not reasonably provide enablement for method of generating catalytic antibody that shows catalytic activity of any enzymatic reaction. Since production of catalytic antibodies dependent on the structure of TS (Mader et al.), and enzymatic reaction depends on the mimicking the TS of bond cleavage or formation of that reaction, as the specification does not teach structures of all the constituents of PCRA claimed in the claims and hence, the TS of peptide bond cleavage reaction, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breath of the claim(s).

Claims 1, 6-7, 11-12,15-23, 25-29, 71-75 encompass method of generating

catalytic antibody by any PCRA comprising any antigenic polypeptide covalently attached to any covalently reactive electrophilic group and inducing said antigen in any organism and wherein said antibodies shows catalytic activity of any enzyme. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of methods of generating catalytic antibodies having any type of transition state (TS) that mimic the transition state of any enzymatic reaction. These claims drawn to method of generating catalytic antibody that shows catalytic activity of any enzyme. The prior art (Taguchi et al. *Biorg and Med chem. Lett*. 2002, 3167-3170) and the specification teach PCRAs (such as compounds in claims 30-33) producing catalytic antibodies eliciting transition state (TS) of a protease type bond cleavage that cleave peptide bond in a protease type polypeptide molecule. The specification or the prior art neither describes all the structures of the components of the PCRA and nor teach how catalytic antibodies produced by said PCRA can shows catalytic activity of any enzyme. In view of the great breaths of claims 1, 6-7, 11-12,15-29, 71-75, amount of experimentation required to illicit antibodies and screening to isolate catalytic antibody molecules that shows the desired catalytic activity of any catalytic activity of any reaction and the lack of guidance, working examples, unpredictability of the art in predicting the function (catalytic activity) from protein's structure (Chica et al. Curr Opin Biotechnol. 2005 Aug; 16(4):378-84), the claimed invention would require undue experimentation. As such the specification fail to teach one of ordinary skill how to use the full scope of the claims.

Thus, applicants have <u>not</u> provided sufficient guidance to enable one of ordinary

skill in the art to make and use any catalytic antibody and method of making catalytic antibody by using PCRA comprising any peptide epitope wherein said catalytic antibodies show catalytic activity of any enzyme. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of PCRA having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

CLAIM Rejection - 35 U.S.C 102

35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8-14 and 16, 24 and 31 are rejected under 35 U.S.C. 102 (a) as being anticipated by Taguchi et al. (*Biorg and Med chem. Lett*. 2002, 3167-3170 , from IDS).

Taguchi et al. teach catalytic antibody raised by using gp120 polypeptide epitope (L of claim 1 having carboxyl functional group of amino acid residue as Y") attached covalently to phosphonate ester (Y reactive electrophilic group, Transition state analogue) which comprise covalently reactive antigen (PCRA) (page 3168 fig 1) and wherein said phosphonate ester moiety bind to the antibody and method of

producing said antibody by inducing said PCRA to mouse (page 3168, column 1, pargh. 3).

Claims 1, 8-14, 16-18, 21-22, 24-29, 71-72 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Paul et al. (US 6235714).

Paul et al. teach catalytic antibody and method of producing said antibody, (monoclonal or polyclonal, single chain Fv fragments, column 16 lines 48-66) by inducing CRAA (column 3 lines 25-45, X1-Y--E-X2, wherein X1, X2 peptide molecule having reactive functional group attached to E electrophonic reactive center that react covalently to a nucleophile, Y is a basic residue of the peptide molecule, CRRA is identical to applicants pCRA) to an organism (MRL/lpr mouse, column 14 lines 45-60) wherein CRA comprise polypeptide epitope attached covalently to phosphonate ester (Transition state analogue) which comprise covalently reactive antigen (PCRA) (figs 4, 10,15- 17 of US6235714). Paul et al. also teach that the antigen molecule comprise tumor necrosis factor, epidermal growth factor receptor, gp120 (claim 4), etc and state that catalytic antibodies produced by said antigens can be used for the treatment of medical disorders like cancer, autoimmune diseases (column 6, lines 1-13, and figs 19A-B)

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-29, 71-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US PAT 6855528. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1, 6-29, 71-75 herein and claim 1 of the US PAT 6855528 are

both directed to a method of generating catalytic antibodies to polypeptide covalently reactive antigen comprise any antigenic polypeptide attached with any reactive covalently attached active center by inducing said antigen in organism such as mouse. The portion of the specification of the US PAT 6855528 that supports the recited method of generating catalytic antibodies to polypeptide covalently reactive antigen comprising antigenic polypeptide attached with reactive covalently attached active center by inducing said antigen in any organism.

Claims 1, 6-29, 71-75 cannot be considered patentably distinct over claim 1 of the US PAT 6855528 when there is a specifically recited embodiment (i.e. method of stimulating production of catalytic antibodies to polypeptide covalently reactive antigen analog comprise antigenic polypeptide attached electrophilic group by inducing said antigen in organism) that would anticipate claims 1, 6-29, 71-75 herein. Alternatively, claims 1, 6-29, 71-75 herein cannot be considered patentably distinct over claim 1 of US PAT 6855528 when there is a specifically disclosed embodiment in US PAT 6855528 that supports claim 1 of that application. US PAT 6855528 teaches catalytic antibodies and method of producing said antibodies (monoclonal, polyclonal, Fv fragments, column 30, lines 11-51, column 31) using antigen PCRA (fig 2, 8, 16) wherein said antigen bind to antibody that resistant to dissociation by 2% SDS (fig 11, column 29, line 20-27, column 30, lines 1-10). US PAT 6855528 also teach that PCRA antigen comprise GP120, tumor necrosis factor (claim 6) and catalytic antibodies produced can be used for treatment of cancer, autoimmune diseases (column 9, lines 24-31) or diseases directed to factor VIII (column 24, lines 35-51). Therefore these embodiments fall within

the scope of claims 1, 6-29, 71-75 herein and it would have been obvious to one having ordinary skill in the art to select the specific antigen analog comprise any antigenic polypeptide attached with electrophilic group and used in the method of claim 1 of the US PAT 7338790 and the recited embodiments in the specification discussed above and pursue the inventions in the claims 1, 6-29, 71-75 of instant application. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 1.

Allowable Subject Matter/Conclusion

Claims 1, 6-33 and 71-75 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NASHAAT T NASHED can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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